

K022481
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AUG 26 2002

Special 510(k) Summary: Line Extension to the S2 Tibial Nail System

Submission Information

Name and Address of the Sponsor of the 510(k) Submission: Howmedica Osteonics Corp
59 Route 17
Allendale, NJ 07401-1677

Contact Person: Karen Ariemma
Regulatory Affairs Specialist

Date of Summary Preparation: July 26, 2002

Device Identification

Proprietary Name: S2 Tibial Nail
Common Name: Intramedullary Nail, Tibial Nail
Classification Name and Reference: Intramedullary Fixation Rod, 21 CFR §888.3020

This Special 510(k) submission is intended to address a line extension to the predicate S2 Tibial Nail System. The line extension involves offering larger diameters of the nail. In addition, Condyle Screws, a Condyle Nut and an additional End Cap will be added to the system. Howmedica Osteonics intends to add the new components to the current product line, thereby offering additional design options for the surgeon. There is no change in intended use for the modified device when compared to the previously cleared device.

Intended Use

The subject S2 Tibial Nail System is a fracture fixation device comprised of tibial nails and the related locking screws, compression screws, end caps, condyle screws and a condyle screw nut. The subject and predicate devices are intended to provide strong and stable internal fracture fixation with minimal soft tissue irritation. This device is utilized as an aid to healing, not as a substitute for normal intact bone and tissue.

Statement of Technological Comparison:

The material used to manufacture the line extension to the S2 Tibial Nail System is identical to that of the predicate. FEA analysis and mechanical testing demonstrates the comparable mechanical properties of the subject S2 Tibial Nail System to the predicate devices.



AUG 26 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Howmedica Osteonics Corporation
Karen Ariemma
Regulatory Affairs Specialist
59 Route 17
Allendale, New Jersey 07401-1677

Re: K022481

Trade/Device Name: S2 Tibial Nail
Regulation Number: 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: July 26, 2002
Received: July 29, 2002

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

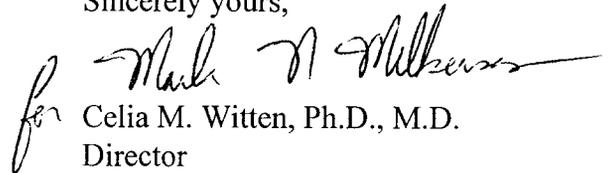
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Karen Ariemma

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K 022481

Device Name: S2 Tibial Nail System

Indications For Use:

The S2 Tibial Nail is intended to provide temporary stabilization of various types of fractures, malunion and nonunion of the tibia. The nails are inserted using an opened or closed technique and can be statically, dynamically and compression locked.

The S2 Tibial Nail System is indicated for long bone fracture fixation, specifically tibial fracture fixation, which may include the following:

- Open and closed tibial fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Nonunion and malunion

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____

OR

Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 10/96)

for Mark H. Mulvaney

(Division Sign-Off)

Division of General Restorative
and Neurological Devices

510(k) Number K022481